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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,884	03/25/2002	Matthew John Baker	IVGN 457	1979

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EXAMINER

SISSON, BRADLEY L

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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05/02/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 09/980,884	Applicant(s) BAKER, MATTHEW JOHN	
	Examiner Bradley L. Sisson	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 January 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24, 26-30 and 3239 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24, 26-30 and 3239 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Prosecution Reopened***

1. In view of the Brief filed on 08 January 2008, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.
2. To avoid abandonment of the application, appellant must exercise one of the following two options:
  - (1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,
  - (2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.
3. A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claim 27 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
6. Claim 27 recites the limitation "the barrel of the syringe" in lines 2-3. There is insufficient antecedent basis for this limitation in the claim.

***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-6, 9, 10, 13-19, 26, 28, 32, and 34-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Stratagene Cloning Systems Catalog (Stratagene; page 81).
9. Stratagene discloses method, reagents and kit for the isolation of RNA and mRNA from tissue. As disclosed at page 81, RNA can be isolated from tissue and passed through a "Quick column" (applicant's cartridge) multiple times. As seen at page 81, the column is reversibly-connected to a syringe, and through the action of the piston in the barrel of the syringe (applicant's reversible suction means), a homogenized sample is caused to pass through the column where messenger RNA (mRNA) is captured by oligo-dT moieties that are bound to cellulose beads.
10. Stratagene, page 81, lower caption, speaks explicitly of passing the sample over the column multiple times. Such a showing is considered to meet the limitation of applicant's

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forcing the fluid over the column in a reverse manner so as to achieve passing the sample over the column multiple times.

11. Stratagene teaches explicitly of the use of reagents of different salt concentrations to wash the bound RNA, and the use of a different buffer to cause the bound RNA to become dissociated from the oligo-dT residues, and ultimately eluted from the column/cartridge.

12. Stratagene teaches explicitly of using a syringe that has a volume of 10 cc. Such a showing meets a limitation of claims 26 and 28.

13. Stratagene teaches explicitly of the syringe being one that has a leur lock so to allow for the releasable connection of the cartridge to the syringe. Such a showing meets a limitation of claims 15, 28 and 38.

### ***Claim Rejections - 35 USC § 103***

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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16. Claims 1-24, 27, 29, 30, and 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stratagene Cloning Systems Catalog (Stratagene; page 81) in view of WO 98/26872 (Blevins) and US Patent 5,453,382 (Novotny et al.).

17. Stratagene discloses method, reagents and kit for the isolation of RNA and mRNA from tissue. As disclosed at page 81, RNA can be isolated from tissue and passed through a "Quick column" (applicant's cartridge) multiple times. As seen at page 81, the column is reversibly-connected to a syringe, and through the action of the piston in the barrel of the syringe (applicant's reversible suction means), a homogenized sample is caused to pass through the column where messenger RNA (mRNA) is captured by oligo-dT moieties that are bound to cellulose beads.

18. Stratagene, page 81, lower caption, speaks explicitly of passing the sample over the column multiple times. However, there is no explicit statement that the multiple passes of the sample liquid through the column is done in a reversible manner.

19. Stratagene also teaches that the cartridge will work with sample volumes of from 200-1000 microliter. Such a showing meets a limitation of claims 3 wherein the container/cartridge/column has a volume "less than or equal to 100 ml."

20. Stratagene teaches explicitly of the use of reagents of different salt concentrations to wash the bound RNA, and the use of a different buffer to cause the bound RNA to become dissociated from the oligo-dT residues, and ultimately eluted from the column/cartridge. Such a showing is considered to meet a limitation of claims 6, 32 and 36 wherein the nucleic acids are removed "from the solid phase by eluting with a solvent."

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21. Stratagene teaches explicitly of using a syringe that has a volume of 10 cc. Such a showing meets a limitation of claims 9 and 28.
22. Stratagene teaches explicitly of the syringe being one that has a leur lock so to allow for the releasable connection of the cartridge to the syringe. Such a showing meets a limitation of claims 15, 28 and 38.
23. Stratagene teaches that the column/cartridge comprises oligo-dT nucleotides bound to cellulose, and that the resulting column can accommodate sample volumes of from 200 to 1000 microliters. Such a showing is considered to meet the limitation of “porous or non-porous beads” of claim 16. The aspect of the column/cartridge having space to accommodate the sample solution speaks directly of there being space allowing for the movement of the solid phase. Such a showing meets a limitation of claim 14. The aspect of the column/cartridge having oligo-dT residues bound to the beads meets a limitation of claim 17 wherein the solid phase comprises “nucleic acid bases,” and also meets a limitation of claim 18 in that the oligo-dT residues “are capable of selectively binding nucleic acid.”
24. The aspect of having the solid support retained in one region of the column/cartridge and yet allowing for the passage of the sample through the solid support, speaks directly to the presence of a frit, porous membrane or mesh- limitations of claims 19 and 37.
25. While Stratagene does teach of passing the sample fluid through the column a plurality of times, Stratagene has not been found to disclose causing the fluid to flow in a reversible manner, even though they are using the very same device, e.g., a syringe. Stratagene has also not been found to teach the use of pipettes.

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26. Blevins discloses a method and related device of the extraction of biochemicals from a sample containing same. As disclosed therein, a pipette is connected to a pipette tip wherein the pipette tip comprises means for binding the biochemical thereto.

27. Blevins, page 4, second full paragraph, teaches explicitly of passing the sample fluid back and forth over the “compartment in the pipette,” adding “[n]aturally, this bidirectional fluid sequence through the pipette and extraction medium may be iterated any number of times with various fluids to enable a greater number of procedures to be conducted.” At page 8, bridging to page 9, Blevins exemplifies the passage of a sample fluid through a solid phase extraction means and then passing the fluid back through said SPEC disc whereby the pipette is used to effect reversible suction means.

28. Blevins also discloses on page 4 that the device and related method may be practiced where multiple compartments and pipettes are employed.

29. Blevins, page 7, teaches that the extraction method and related device can be designed to bind “desired analytes from a given sample” by altering the solid phase used in the compartment.

30. Novotny et al., Figure 1, depicts a syringe connected to a container wherein analytes of interest can bind.

31. Novotny et al., column 6, list a plethora of suitable biological samples.

32. Novotny et al., column 6, lines 38-40, also teach of the “packing material” (applicant’s “solid phase”) being held in place through use of a frit. Said frit is considered to meet the limitations of claims 19, 20, and 30.

33. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Stratagene with that of Blevins wherein the repeated



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passage of the sample through the container (column/cartridge/pipette), as disclosed by Stratagene, is done in a reversible manner, as disclosed by Blevins, as such would have allowed for increased exposure of the sample to the solid phase without necessitating the removal of the cartridge from the reversible suction means (e.g., syringe). It would have also been obvious to one of ordinary skill in the art at the time the invention was made to have adapted or modified the reversible suction means of Stratagene with that of Novotny et al., such that other common laboratory fluid handling/manipulating devices, such as a pipette, was used to contain the solid phase and be used in a method of binding a target analyte, as is explicitly disclosed by both Stratagene and Novotny et al.

34. In view of the detailed teachings, and explicit guidance for the capture and elution of the same nucleic acids by the same means, the claimed method and device are deemed to be fairly suggested by the prior art of record. Therefore, and in the absence of convincing evidence to the contrary, claims 1-24, 27, 29, 30, and 32-39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stratagene Cloning Systems Catalog (Stratagene; page 81) in view of WO 98/26872 (Blevins) and US Patent 5,453,382 (Novotny et al.).

### ***Conclusion***

35. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

36. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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37. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

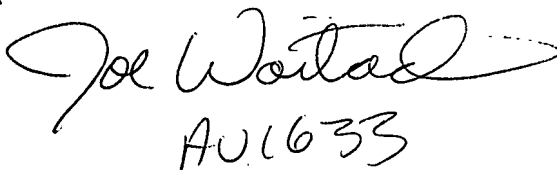
38. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Bradley L. Sisson  
Primary Examiner  
Art Unit 1634

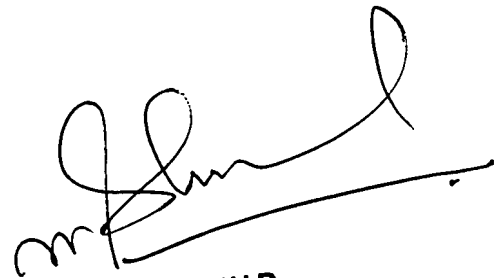
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